#

J. DWIGHT POFFENBERGER, JR.

C. RICHARD EBY

DAVID E. PRITCHARD

DAVID H. BRINKMAN

KRISTI L. DAVIDSON

DAVID E. JEFFERIES

DAVID E. FRANKLIN

JOHN PAUL DAVIS DOUGLAS A. SCHOLER

BRETT A. SCHATZ

ALLISON A. DAVIDSON

TECHNICAL ADVISORS

HENRY M LABODA Ph.D.

LARRY D. MOORE, B.S.E.E.

DAVID W. DORTON, M.M.E. RONALD J. RICHTER, M.D. G. PRABHAKAR REDDY, M.S.CH.

BEVERLY A. LYMAN, Ph.D. KATHRYN E. SMITH

P. ANDREW BLATT, Ph.D.

WILLIAM R. ALLEN. Ph.D.

FRANK M. MUNGO (KY BAR)

WOOD, HERRON & EVANS, LL.P.

2700 CAREW TOWER

441 VINE STREET

CINCINNATI, OHIO 45202-2917

TELEPHONE: 513-241-2324

FACSIMILE: 513-421-7269

EMAIL: info@whepatent.com

PATENT, TRADEMARK, COPYRIGHT AND UNFAIR COMPETITION LAW AND RELATED LITIGATION

> EDMUND P. WOOD 1923-1968 TRUMAN A. HERRON 1935-1976 EDWARD B. EVANS 1936-1971

November 13, 2001
VIA HAND DELIVERY

VTRO-28

Karin Tyson, Esquire Senior Legal Advisor United States Patent and Trademark Office Crystal Plaza 3 Washington, D.C. 20231

Re.

JOHN D. POFFENBERGER

BRUCE TITTEL

DONALD F. FREI

DAVID J. JOSEPHIC

DAVID S. STALLARD

GREGORY J. LUNN KURT L. GROSSMAN

THOMAS J. BURGER

WAYNE L. JACOBS

KURT A. SUMME KEVIN G. ROONEY

GREGORY F. AHRENS

A. RALPH NAVARO, JR.

J. ROBERT CHAMBERS

CLEMENT H. LUKEN, JR.

KEITH R. HAUPT THEODORE R. REMAKLUS

THOMAS W. HUMPHREY

SCOTT A. STINEBRUNER

Term Extension of United States Patent No. 4,490,351

VITREON®

Dear Ms. Tyson:

Thank you for your continued assistance in our Request for Term Extension for the above-referenced patent. We share your quest to obtain information from the Food and Drug Administration (FDA Docket No. 98E-0849), and truly appreciate your continual efforts in this regard. We, too, have been frustrated in our repeated attempts to define the problem and/or to resolve this matter satisfactorily to allow the FDA to forward the case to the United States Patent and Trademark Office.

Our understanding is that the FDA's final determination of the regulatory review period is to be republished by the FDA in the *Federal Register*. It is our understanding that you are in contact with Ms. Grillo at the FDA but, to date, no publication has occurred. You have also been monitoring the *Federal Register*. Once publication has occurred, the United States Patent and Trademark Office can then prepare a Notice of Final Determination, indicating the length of the patent term adjustment, and the information to be printed for publication in the *Official Gazette*.

Please let us know if our understanding is incorrect. We otherwise very much appreciate your continued assistance and updates in this matter.

Very truly yours,

Beverly A. Lyman, Ph.D.

Beruly A. Lyman

BAL:cmp

cc: Mr. Edward M. Beranek

David J. Josephic, Esquire

K:\VTRO\28\LTR Tyson status patent term extension.wpd